

Dockets Management Branch (HFA-305)
Docket No. 98N-1265 6.9 '99 MAR 24 A9:45
Food and Drug Administration
5600 Fishers Lane
Rockville, MD. 20857

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Lola Hess
Signature

3/17/99
Date

I used to live in Wisconsin but moved to Michigan. I am a customer of Women's Health America, Inc of Madison, Wisconsin.

COMMENTS: The use of compounded testosterone has helped the quality of my life. It is available nowhere else now but at compounding pharmacies. I used to have 10 mg. of retin methyltest prescribed for me, which is for men, and I had to cut each pill into quarters to get 2.5 mg, which was still probably too high of a dose for a woman. The compounding centers fill a niche market. I did not receive relief from my menopause symptoms by using only premarin. Now Wyeth-Ayerst does not make methyltestosterone any more.

No one - no commercial manufacturers of pharmaceuticals make it anymore.

It helps relieve my symptoms of vaginal atrophy. It makes

98N-1265 me wonder why do men have viagra available if, without my testosterone compound, intercourse will be physically impossible? I can not be alone with this problem. Why has no testing or research been done about the affect of

Please fold, seal, and mail by March 22

lack of testosterone in post menopausal women? It also improves bone density, libido as well as vaginal atrophy. I don't think medicine should be "one size fits all." The compounding pharmacies customize prescriptions.



John & Lola Hess
5105 Amberwood Ct.
Midland, MI 48640-7416



**DOCKETS MANAGEMENT BRANCH (HFA-305)
DOCKET NO. 98N-1265
FOOD AND DRUG ADMINISTRATION
5600 FISHERS LANE
ROCKVILLE, MD. 20857**